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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,694	04/09/2004	Christa Harris	THR-6198UTIL	1151

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ALLEGIANCE CORPORATION

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EXAMINER

ROANE, AARON F

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 08/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/821,694	HARRIS, CHRISTA	
	Examiner	Art Unit	
	Aaron Roane	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-8 and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheney, III (USPN 5,143,048) in view of Silver (USPN 5,897,580) in further view of Manker (USPN 5,800,492).

Regarding claims 1 and 4, Cheney, III discloses an infant heel warming device (10) comprising: an exothermic thermochemical composition (15) wherein the exothermic reaction occurs upon activation, see col. 1-4 and figures 1-4. Cheney, III fails to disclose a flexible polymeric containment for said thermochemical composition, said containment being structured to have a first skin-contacting side and second transparent viewing side, each of said first and second sides having an interior surface and exterior surface; wherein said first skin-contacting side of said containment further comprises an outer fabric layer attached onto said skin-contacting side surface. Cheney, III also fails to

disclose at least one securing strap is attached to said device to secure said device onto the foot. Silver discloses a warming device (10) comprising: an exothermic thermochemical composition (26) wherein the exothermic reaction occurs upon activation; a flexible polymeric containment (10 composed of layers 12 and 14) for said thermochemical composition. Silver teaches providing a containment being structured to have a first skin-contacting side (12) and second transparent viewing side (14), each of said first and second sides having an interior surface and exterior surface in order to locate the triggering element. Additionally, Silver teaches providing said first skin-contacting side of said containment with an outer fabric layer (30) attached onto said skin-contacting side surface in order to provide extra comfort to the user, see col. 1-6, particularly col. 2, line 10 through col. 5, line 23 and figures 1-7. Manker discloses an adhesive warming bag (10) and teaches providing the bag (10) with at least one strap (14) in order to properly secure the bag to an infant's foot, see col. 3 and figures 1-6.

Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Cheney, III, as taught by Silver, to provide a flexible containment being structured to have a first skin-contacting side and second transparent viewing side in order to contain the heating composition and in order to locate the triggering element, and as also taught by Silver, to provide the first skin-contacting side of said containment with an outer fabric layer attached onto said skin-contacting side surface in order to provide extra comfort to the user, and as finally taught by Manker, to providing the device with at least one strap in order to properly secure the bag to an infants foot.

Regarding claim 3, Cheney, III in view of Silver in further view of Manker disclose the claimed invention. Silver further discloses said second viewing side is composed of a transparent polymeric material permitting viewing of the interior of said flexible polymeric containment, see col. 3, lines 6-19.

Regarding claims 5 and 6, Cheney, III in view of Silver in further view of Manker disclose the claimed invention. Silver further discloses the claimed invention, see col. 4, lines 38-56 and figure 7. Additionally, it should be noted the recitation of the outer fabric layer adhered onto said first skin-contacting side by an adhesive, is interpreted as a method of manufacture. The determination of patentability in a product-by-process claim is based on the product itself, even though the claim may be limited and defined by the process. That is, the product in such a claim is unpatentable if it is the same as or obvious from the product of the prior art, even if the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985). A product-by-process limitation adds no patentable distinction to the claim, and is unpatentable if the claimed product is the same as a product of the prior art.

Regarding claims 7 and 8, Cheney, III in view of Silver in further view of Manker disclose the claimed invention. Silver further discloses said outer fabric layer is composed of a non-woven material made from rayon, see col. 4, lines 38-46.

Art Unit: 3739

Regarding claims 11-15, Cheney, III in view of Silver in further view of Manker disclose the claimed invention. Silver further discloses the claimed invention. In col. 4, lines 23-32, Silver incorporates by reference Stanley et al. (USPN 4,077,390), Fiedler (USPN 4,572,158) and Manker (USPN's 4,872,442, 4,880,953 and 5,058,563). Manker (USPN 4,872,442) discloses the claimed invention, see entire reference.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheney, III (USPN 5,143,048) in view of Silver (USPN 5,897,580) in further view of Manker (USPN 5,800,492) as applied to claim 1 above, and further in view of Angelillo et al. (USPN 5,736,110).

Regarding claim 9, Cheney, III in view of Silver in further view of Manker disclose the claimed invention except for reciting the thermochemical composition comprises a liquid mixture of sodium acetate trihydrate and water. Silver does state "the chemical composition 26 may be any chemical or mixture of chemicals that undergoes an exothermic reaction. Preferably the exothermic reaction is reversible," see col. 4, lines 12-22. It is extremely well known in the art that sodium acetate trihydrate is used in thermal devices wherein the application of thermal energy is triggered by a physical activator. Angelillo et al. disclose a thermal device that is triggered and teach the use of super saturated sodium acetate trihydrate in order to provide reusable heating, see col. 6-11. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Cheney, III in view of Silver in further view of

Manker, as is known in the art and taught by Angelillo et al., to use super saturated sodium acetate trihydrate in order to provide reusable heating.

Regarding claim 10, Cheney, III in view of Silver in further view of Manker in still further view of Angelillo et al. disclose the claimed invention. Cheney, III in view of Silver in further view of Manker in still further view of Angelillo et al. is silent as to the ratio of sodium acetate trihydrate to water other than the sodium acetate trihydrate is super saturated (large amount of sodium acetate trihydrate to small amount of water). At the time of the invention, it would have been an obvious matter of design choice to one of ordinary skill in the art to use a mixture of sodium acetate trihydrate present in an amount of about 73% of the total liquid volume and water present in an amount of about 27% of the total liquid volume because Applicant has not disclosed this particular ratio provides an advantage, is used for a particular purpose, or solves a stated problem compared to a simple super saturated solution of sodium acetate trihydrate and water. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a simple super saturated solution of sodium acetate trihydrate and water or a mixture of sodium acetate trihydrate present in an amount of about 73% of the total liquid volume and water present in an amount of about 27% of the total liquid volume because they both provide the necessary reusable heat source though the physical activation of the trigger.

Response to Arguments

Applicant's arguments filed 4/25/2006 have been fully considered but they are not persuasive. The examiner will only address the arguments/remarks regarding the 103 rejections as Applicant has amended the only independent claim, claim 1.

Beginning at the bottom of page 6 and continuing until the next to last paragraph on page 9, Applicant refutes the combination of Cheney, III in view of Silver in further view of Manker. On page 7, lines 11-14 Applicant refutes the combination of Cheney, III and a breast warming device (Silver), "it is not understood, however, why one of ordinary skill in the infant heel warming art would turn to features pertaining to a breast warming device and view such as modifications suitable for a device to be attached to an infant's foot." Both Cheney, II and Silver pertain to thermal application devices, are analogous art and therefore it would be obvious to one of ordinary skill in the art to combine the references because of what the prior art as a whole would have suggested to one of ordinary skill in the art.

In the last two paragraphs on page 7, Applicant refutes the Manker and Silver references respectively. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Finally, in the first full paragraph on page 8, Applicant asserts "none of these references alone or in combination would have lead one of ordinary skill in the art to arrive at Applicant's invention." However, the test for obviousness is not whether the features of a secondary

Art Unit: 3739

reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F. 2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In this regard, a conclusion of obviousness may be based on common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. In re Bozek, 416 F. 2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969).

This action is made FINAL.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 3739

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 7AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A.R. *A.R.*
August 1, 2006

Roy D. Gibson
ROY D. GIBSON
PRIMARY EXAMINER